

**REMARKS**

Claims 1-24 are pending in the application. Favorable re-consideration is requested.

At the outset, applicant respectfully requests the withdrawal of the "finality" of the Office Action because the current rejections were not stated in the previous Office Action despite the fact that the claims are the same or essentially the same under U.S. law with respect to the prior art contentions. See, for example, claim 1 that covers the same subject matter as previously claimed. Moreover, the Givens reference was never cited previously. Thus, applicant never had a chance to address these new rejections and the Givens reference under a "non-final" situation.

The following new prior art rejections have been asserted against the claims:

1. In paragraph number 1 on pages 2-6 of the Office Action, Claims 1-6, 8-9, 12, 14, 17-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Dadson (US Patent 6228047) in view of Givens et al. (US Pg Pub 2002/0010553).
2. In paragraph number 4 on pages 6-7 of the Office Action, Claims 7, 10, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson and Givens in view of Klein et al. (US Patent 4244787).
3. In paragraph number 5 on page 7-8 of the Office Action, Claims 13 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson and Givens in view of Suzuki et al. (US Patent 6595948).
4. In paragraph number 6 on pages 8-9 of the Office Action, Claims 15 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dadson and Givens in view of Skeggs (US Patent 2797149).

Applicant respectfully traverses the rejections at least for the following reasons.

The first rejection is an improper anticipation rejection because "anticipation" requires that all elements be found in one reference -- not a combination of two references (Dadson and Givens). Consequently, applicant requests the withdrawal of this improper "anticipation" rejection.

All four of the rejections combine the Dadson reference with the newly cited Givens reference as the basis for all of the rejections. Significantly, in the middle of page 9 of the Office Action, the examiner agrees that Dadson fails to disclose applicant's claimed multiple sampling chambers, but then the examiner asserts that this distinguishing feature is moot in view of the new prior art rejections based on Givens. Applicant has two main responses to this assertion and the obviousness rejections.

First, applicant is "swearing behind" the newly cited Givens publication date of January 2002 in view of applicant's conception of its invention prior to the January 2002 publication date of Givens and applicant's diligent preparation and filing of its priority application on January 28, 2002. A Rule 131 Declaration is being submitted in support of these facts. As a result, all of the rejections should be withdrawn, and this application passed to allowance.

Second, the Section 103 rejections are not proper because one skilled in the art could not combine the cited references in any "reasonable apparent" way and arrive at the claimed invention.

Applicant again notes that the primary reference (Dadson) is a family member of International Application No. WO 99/06082, a copy of which has already been submitted to the USPTO. Both the Dadson U.S. patent and the International application have the same or similar content. The Dadson WO reference was identified by the International Bureau during the PCT phase. The IPER, which was very positive, thoroughly discussed the Dadson WO reference. Applicant previously submitted a copy of the IPER with an Information Disclosure Statement.

In the IPER on file in this case, the examiner correctly stated that "the subject matter of [applicant's] claim 1 differs from [the WO reference, i.e., the Dadson reference] in that the

[applicant's] automatic peritoneal sampling system comprises MULTIPLE sampling containers and the series of valves are used to fill each of these containers" (emphasis added). Thus, the examiner determined that claim 1 was novel. The same is true in this U.S. patent application because it concerns the same claim features and the same cited Dadson reference/disclosure.

In addition, as noted in the IPER, the examiner stated that claim 1 was not obvious because "the differentiating features mentioned above have the purpose of automatically preparing and storing separate samples of dialysate liquid for later analysis. None of the available prior art documents describes the physical storing of a plurality of dialysate liquid samples for later use, neither before nor after each sample has been analyzed." These statements are absolutely correct and confirm that the claimed invention is not obvious in view of Dadson either alone or in any "reasonably apparent" combination with any other known prior art. As stated by the Supreme Court in *KSR*, there must be a "reasonably apparent" way to combine references that would yield the claimed invention. In this case, the primary reference, Dadson, fails to disclose or suggest the foregoing claimed features, and the other references do not overcome those deficiencies because they also lack any disclosure or teaching of the foregoing claimed features or any apparent reason for combining their teachings with Dadson's teachings to arrive at the claimed invention. Thus, the claimed invention is patentable over any of the cited references either individually or in any "reasonably apparent" combination. Accordingly, applicant requests the withdrawal of the obviousness rejections.

In further support of applicant's position, the Dadson reference is clearly limited to the use of a single sampling container. No discussion or incentive regarding the use of several sampling containers is disclosed in Dadson. Moreover, the newly cited Givens reference does

not relate to peritoneal dialysis. Thus, one skilled in the art would have no incentive or reason to combine the teachings of these two references and arrive at the claimed invention.

Moreover, and respectfully stated, the examiner has incorrectly interpreted the Dadson disclosure by confusing the drain phase and the collection phase. In this regard, Dadson teaches how to mix different liquids and administering them to the patient, while using the same pumping method in order to drain the liquid from the patient at the end of a cycle (column 3 line 34-35 & 43-48 & 53-54 & column 4 line 50). Only in an exceptional case (column 4 line 59-60) is a collector used for a specific purpose of collecting a cloudy sample in the event of suspicion of peritonitis (column 11 line 27-29 & 39-40) based on a turbidity measurement described in claim 16. One must not get confused between the collector container 30 and the receptacle for drain liquid (column 12 line 18 & 23, column 14 line 12-17) which later is only a general collector for drain liquid which will later be discarded, contrary to the collecting sample which will be analyzed. This is quite different than the claimed invention.

Furthermore, Dadson's pharmacokinetics described in column 9 (line 24-27) are based on the pressure measurement resulting from the ultrafiltration, and not based on measured characteristics of the content of the fluid as the applicant's claimed invention -- which requires multiple samples. Indeed, and contrary to Dadson's teachings, applicant's claimed invention does not work with only one sample because applicant's invention needs to measure a kinetic that requires at least two points. The description of the method taught by Dadson can be found in column 9 line 6-14 as well as in column 7 line 16-67 and column 8 line 1-9, where Dadson uses the pressure as a means to address the patient changes due to UF and osmotic exchanges.

In fact, the only example given by Dadson relative to sample collection is in column 9 line 28-54. However, this relates to one sample collection (possibly of multiple samples in the

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same collector?) during the DWELL at known correlated points on the UF curve (line 50-51), i.e., in relation with the pressure measurement -- which is very different from a pharmacokynetic study as per applicant's invention. The mixing of multiple samples in one collector can be made under Dadson because it is NOT a PHARMACOKYNETIC study.

For at least the foregoing reasons, the obviousness rejections are not proper because one skilled in the art would not combine the cited references in any "reasonably apparent" way and arrive at the claimed invention. As a result, applicant requests the withdrawal of the obviousness rejections.

Applicant respectfully submits that this application is in condition for allowance. A notice to that effect is earnestly solicited.

If the Examiner has any questions concerning this case, the undersigned may be contacted at 703-816-4009.

Respectfully submitted,

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